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REMARKS

Favorable reconsideration of this application is respectfully requested in view of the above amendments and following remarks. Claims 1 and 11 are amended and are supported throughout Applicants' disclosure, for example at page 11, lines 23-25. No new matter has been added. Claims 1, 8-12, 14, and 16 are pending.

Claims 1, 8-12, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eda et al. (US 6248597) in view of Shigenobu et al. (WO 02/018953, EP 1314982) and in further view of Craig et al. (US 4401765). Applicants respectfully traverse this rejection to the extent it is maintained.

The rejection contends unexpected results have not been shown, and that motivation to combine the references is in the nature of the problem to be solved, rendering the claimed invention obvious. Applicants respectfully disagree. Applicants respectfully contend that the claimed invention exhibits superior results, and that there is no motivation to combine the cited references. Claims 1 and 11 are not obvious for at least the following reasons.

Shigenobu et al. is cited as suggesting the use of particular polymer materials recognized to be missing from Eda et al. Shigenobu et al. discloses a polymer having a monomer unit derived from a monomer, such as 2-methacryloyloxyethyl phosphorylcholine (hereinafter "MPC polymer"), and discloses a copolymer obtained by polymerizing the monomer 2-methacryloyloxyethyl phosphorylcholine with a "second" monomer selected from the group consisting of (meth)acrylates such as acrylate ester, a methacrylate ester, butyl methacrylate, or styrene derivatives. Shigenobu et al. provides examples using the copolymer of MPC polymer and n-butyl methacrylate (polymers 1-3), and examples using the homopolymer of MPC polymer (polymers 4-5). (See also page 5, paragraph [0014].) However, Shigenobu et al. does not teach or suggest the use of polymers of aralkyl methacrylate monomers as required by claims 1 and 11, and there is no reasonable expectation that the polymers of Shigenobu et al. would perform as those of the claimed invention.

Table 1 of Applicants' disclosure further supports this position, where the results of the claimed invention are compared to corresponding polymers of Shigenobu et al. (See for example Applicants' page 21.) Table 1 below shows the polymer 1, the polymer

5, and the polymer 6 used as agglutination accelerators. The polymer 5 is a polymer satisfying the features of claims 1 and 11. The polymer 1 and the polymer 6 correspond to the polymers used in Shigenobu et al., and respectively are the copolymer of MPC polymer and n-butyl methacrylate and the homopolymer of MPC polymer. From the results shown in Table 1, the polymer 5 enjoys increased absorbance values than the other polymers, and namely gives the best agglutination accelerator effect. Thus, from the results of Table 1, the claimed invention is clearly superior to the polymers disclosed in Shigenobu et al for an assay of PSA.

Table 1

PSA (ng/ml)	Without Agglutination accelerator	Example 1			Comp. Example 1
		Polymer 1	Polymer 5	Polymer 6	PEG 6000
2	37	71	90	60	75
10	160	512	605	296	292
50	817	5483	5824	2440	1914
Difference between 2ng/ml and 10ng/ml	123	441	515	236	217

Furthermore, it is well known that a cutoff concentration value of PSA is usually set in the range of about 1.8 to about 4.0 ng/ml. (See Table 2 of *Prostate-Specific Antigen as a Tumor Marker in Prostate Cancer*, Int. J. Urol 1994:1:99-113, submitted herewith.) The claimed invention is particularly desirable in such low concentration ranges typically employed when conducting an assay of PSA. Referring again to Table 1, the absorbance results in the concentrations of 2 ng/ml and 10 ng/ml further illustrate that the claimed invention can be optimal for an assay of PSA. That is, the results of using the polymer 5 compared with that of the polymer 1 is increased by about 27% and about 18%, respectively, while the results of using the polymer 5 with that of the polymer 6 is increased by about 50% and about 104%, respectively. Thus, the polymer 5 has greater effect to improve detection sensitivity than the polymers 1 and 6.

Additionally, when comparing the absorbance values of the difference between the 2ng/ml and 10ng/ml concentrations, namely, the absorbance values obtained by increasing the concentration 8ng/ml, the results of using the polymer 5 is increased by

about 17% compared with that of the polymer 1, and is increased by about 118% compared with that of the polymer 6. (See added row calculation of Table 1 above.) Thus, the polymer of the claimed invention can provide increased absorbance values by at least 17% in such concentrations in which PSA is usually assayed, as opposed to the polymers disclosed in Shigenobu et al.

Moreover, Applicants provide further experimental data to demonstrate the superior effect of the claimed invention. In the Declaration under Rule 1.132 submitted herewith, Applicants' show data of variation (n=5) of blank values when using polymers 1, 5 and 6.

(ng/ml)	Polymer5	Polymer1	Polymer6
1st	4	5	12
2nd	3	3	-4
3rd	-4	-8	-11
4th	-3	5	6
5th	2	-5	-5
Variation	8	13	23

As is clear from the above results, blank value obtained by using the polymer 1 shows a level of variation about 1.5 times that obtained by using the polymer 5. Blank value obtained by using the polymer 6 shows a level of variation about 3 times that obtained by using the polymer 5. While an agglutination accelerator can generally improve measurement sensitivity, levels of variation in blank value typically increase as well. However, the claimed invention can provide a significant improvement by both improving sensitivity as discussed above, while also reducing the level of variation in blank value. As illustrated in the experimental data, the polymer 5 shows more agglutination accelerator effect and has little influence on blank value, than polymers 1 and 6. Therefore, the claimed invention provides an assay that can be performed with high precision and high sensitivity since measurement sensitivity is improved, and the polymer used has little influence on blank value.

For at least the foregoing reasons, Example 1 of Applicants' disclosure clearly demonstrates that the polymer of the claimed invention is superior as an agglutination accelerator for an assay of PSA than the polymers disclosed in Shigenobu et al. The superior results mentioned above are found for the first time by Applicants. The effects

mentioned above would not reasonably be expected by one of the skill in the art, because Shigenobu et al. teaches neither the polymer of the claimed invention, nor the effects of the polymer or the effect of the assay of PSA. Therefore, Shigenobu et al. does not teach or suggest the claimed invention, and there is no reasonable expectation that the polymers of Shigenobu et al. would perform as that of the claimed invention.

Referring to Craig et al., this reference does not further the rejection and is not relevant to the claims. Craig et al relates to a particular particle reagent for light scattering immunoassays. The reference discloses that, with regard to a core polymer in a particle reagent, polymers with high aromaticity such as benzyl methacrylate are preferred over aliphatic polymers, because of their high refractive indices. That is, the core polymer in Craig et al is a particle, such as latex for immobilizing an antibody in the agglutination assay, and is meant to be a solid that is insoluble in a reagent. However, Craig et al. does not disclose a polymer as an agglutination accelerator.

In contrast, claims 1 and 11 require a copolymer as an agglutination accelerator, and dissolved in a reagent. The polymer of the present invention gives the effect for accelerating the agglutination reaction when the agglutination reaction used with latex is conducted in the presence of the polymer of the present invention. However, Craig et al. is not directed at the same problem as the claimed invention, because the reference uses its polymer for a clearly different purpose than the claimed invention. There is no reasonable suggestion or motivation for combining Craig et al. with Eda et al. and Shigenobu et al. for at least the foregoing reasons. Applicants respectfully submit that the references do not teach or suggest the features of claims 1 and 11, and would not enjoy the effects that may be expected from the claimed invention. Thus, claims 1 and 11 and their dependents are not obvious.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above amendments and remarks, Applicants believe that the pending claims are in a condition for allowance. Favorable consideration in the form of a Notice of Allowance is respectfully solicited. If any questions arise regarding this communication, the Examiner is invited to contact Applicants' representative listed below.

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

Dated: December 27, 2006

By: _____
Douglas P. Mueller
Reg. No. 30,300
DPM/baw